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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,682	01/10/2001	Fahri Saatcioglu	586.02-US1	6146

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EXAMINER

RAWLINGS, STEPHEN L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/15/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,682

Applicant(s)

SAATCIOGLU, FAHRI

Examiner

Stephen L. Rawlings, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>9</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input checked="" type="checkbox"/> Other: <i>Election facsimile cover sheet</i> . |

DETAILED ACTION

1. Claims 1-36 are pending in the application and are currently subject to restriction.
2. As noted in the attached interview summary of July 9, 2002 (Paper No. 9), numerous inadvertent errors were made in the restriction requirement mailed March 20, 2002 (Paper No. 8), which have clearly caused Applicant some confusion. Accordingly, the previous restriction requirement mailed March 20, 2002 is withdrawn and substituted by the restriction requirement set forth below. The Examiner regrets any inconvenience that this has caused the Applicant.

Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 5-10, and 13-20, insofar as the claims are drawn to a polynucleotide comprising a nucleotide sequence that is at least 90% identical to the nucleotide sequence set forth in SEQ ID NO: 3, a polypeptide comprising an amino acid sequence that is at least 90% homologous to the amino acid sequence set forth in SEQ ID NO: 10, and a method for detecting a neoplastic cell, said method comprising correlating an RNA comprising SEQ ID NO: 17 with a presence of a neoplastic cell.

Group II, claim(s) 3, 7, 8, 33, and 35, insofar as the claims are drawn to a polynucleotide comprising a nucleotide sequence that is at least 90% identical to the nucleotide sequence set forth in SEQ ID NO: 4.

Group III, claim(s) 4, 7, 8, 34, and 36, insofar as the claims are drawn to a polynucleotide comprising a nucleotide sequence that is at least 90% identical to the nucleotide sequence set forth in SEQ ID NO: 7.

Group IV, claim(s) 11, 13, and 14, insofar as the claims are drawn to a polypeptide comprising an amino acid sequence that is at least 90% identical to the nucleotide sequence set forth in SEQ ID NO: 11.

Group V, claim(s) 12-14, insofar as the claims are drawn to a polypeptide comprising an amino acid sequence that is at least 90% identical to the nucleotide sequence set forth in SEQ ID NO: 14.

Group VI, claim(s) 15-20, insofar as the claims are drawn to a method for detecting a neoplastic cell, said method comprising correlating an RNA comprising SEQ ID NO: 18 with a presence of a neoplastic cell.

Group VII, claim(s) 15-20, insofar as the claims are drawn to a method for detecting a neoplastic cell, said method comprising correlating an RNA comprising SEQ ID NO: 21 with a presence of a neoplastic cell.

Group VIII, claim(s) 15-20, insofar as the claims are drawn to a method for detecting a neoplastic cell, said method comprising correlating an RNA comprising SEQ ID NO: 17 and SEQ ID NO: 18 with a presence of a neoplastic cell.

Group IX, claim(s) 15-20, insofar as the claims are drawn to a method for detecting a neoplastic cell, said method comprising correlating an RNA comprising SEQ ID NO: 17 and SEQ ID NO: 21 with a presence of a neoplastic cell.

Group X, claim(s) 15-20, insofar as the claims are drawn to a method for detecting a neoplastic cell, said method comprising correlating an RNA comprising SEQ ID NO: 18 and SEQ ID NO: 21 with a presence of a neoplastic cell.

Group XI, claim(s) 15-20, insofar as the claims are drawn to a method for detecting a neoplastic cell, said method comprising correlating an RNA comprising SEQ ID NO: 17, SEQ ID NO: 18, and SEQ ID NO: 21 with a presence of a neoplastic cell.

Group XII, claim(s) 21-26, insofar as the claims are drawn to a method for detecting a neoplastic cell, said method comprising correlating an intracellular polypeptide comprising SEQ ID NO: 10 with a presence of a neoplastic cell.

Group XIII, claim(s) 21-26, insofar as the claims are drawn to a method for detecting a neoplastic cell, said method comprising correlating an intracellular polypeptide comprising SEQ ID NO: 11 with a presence of a neoplastic cell.

Group XIV, claim(s) 21-26, insofar as the claims are drawn to a method for detecting a neoplastic cell, said method comprising correlating an intracellular polypeptide comprising SEQ ID NO: 14 with a presence of a neoplastic cell.

Group XV, claim(s) 21-26, insofar as the claims are drawn to a method for detecting a neoplastic cell, said method comprising correlating an intracellular polypeptide comprising SEQ ID NO: 10 and SEQ ID NO: 11 with a presence of a neoplastic cell.

Group XVI, claim(s) 21-26, insofar as the claims are drawn to a method for detecting a neoplastic cell, said method comprising correlating an intracellular polypeptide comprising SEQ ID NO: 10 and SEQ ID NO: 14 with a presence of a neoplastic cell.

Group XVII, claim(s) 21-26, insofar as the claims are drawn to a method for detecting a neoplastic cell, said method comprising correlating an intracellular polypeptide comprising SEQ ID NO: 11 and SEQ ID NO: 14 with a presence of a neoplastic cell.

Group XVIII, claim(s) 21-26, insofar as the claims are drawn to a method for detecting a neoplastic cell, said method comprising correlating an intracellular polypeptide comprising SEQ ID NO: 10, SEQ ID NO: 11, and SEQ ID NO: 14 with a presence of a neoplastic cell.

Group XIX, claim(s) 27-32, drawn to a method for identifying differentially expressed genes.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. The inventions listed as Groups I-XIX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I is the polynucleotide sequence set forth in SEQ ID NO: 3.

The special technical feature of Group II is the polynucleotide sequence set forth in SEQ ID NO: 4.

The special technical feature of Group III is the polynucleotide sequence set forth in SEQ ID NO: 7.

The special technical feature of Group IV is the polypeptide sequence set forth in SEQ ID NO: 11.

The special technical feature of Group V is the polypeptide sequence set forth in SEQ ID NO: 14.

The special technical feature of Group VI is detecting the polynucleotide sequence set forth in SEQ ID NO: 18.

The special technical feature of Group VII is detecting the polynucleotide sequence set forth in SEQ ID NO: 21.

The special technical feature of Group VIII is detecting the polynucleotide comprising SEQ ID NO: 17 and SEQ ID NO: 18.

The special technical feature of Group IX is detecting the polynucleotide comprising SEQ ID NO: 17 and SEQ ID NO: 21.

The special technical feature of Group X is detecting the polynucleotide comprising SEQ ID NO: 18 and SEQ ID NO: 21.

The special technical feature of Group XI is detecting the polynucleotide comprising SEQ ID NO: 17, SEQ ID NO: 18, and SEQ ID NO: 21.

The special technical feature of Group XII is detecting the polypeptide comprising SEQ ID NO: 10.

The special technical feature of Group XIII is detecting the polypeptide comprising SEQ ID NO: 11.

The special technical feature of Group XIV is detecting the polypeptide comprising SEQ ID NO: 14.

The special technical feature of Group XV is detecting the polypeptide comprising SEQ ID NO: 10 and SEQ ID NO: 11.

The special technical feature of Group XVI is detecting the polypeptide comprising SEQ ID NO: 10 and SEQ ID NO: 14.

The special technical feature of Group XVII is detecting the polypeptide comprising SEQ ID NO: 11 and SEQ ID NO: 14.

The special technical feature of Group XVIII is detecting the polypeptide comprising SEQ ID NO: 10, SEQ ID NO: 11, and SEQ ID NO: 14.

The special technical feature of Group XIX is identifying differentially expressed genes.

Accordingly, the groups of inventions are not linked by the same or a corresponding special technical feature so as to form a single general inventive concept. Furthermore, PCT Rules 13.1 and 13.2 do not provide for unification of more than the first claimed product, the first claimed method of making said product, and the first claimed method for using said product.

6. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Species A, claim 25, drawn to the method of claim 24 wherein the probe is an antibody or an antibody fragment.

Species B, claim 25, drawn to the method of claim 24 wherein the probe is a natural ligand of the polypeptide.

Species C, claim 25, drawn to the method of claim 24 wherein the probe is a synthetic ligand of the polypeptide.

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7. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The special technical feature of Species A is an antibody or an antibody fragment.

The special technical feature of Species B is a natural ligand of a polypeptide.

The special technical feature of Species C is a synthetic ligand of a polypeptide.

Accordingly, the species of invention are not linked by the same or a corresponding special technical feature so as to form a single general inventive concept.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Stephen L. Rawlings, Ph.D.

Examiner

Art Unit 1642

slr

July 9, 2002



DONNA WORTMAN
PRIMARY EXAMINER

Intervi w Summary	Application No.	Applicant(s)	
	09/743,682	SAATCIOGLU, FAHRI	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

All participants (applicant, applicant's representative, PTO personnel):

(1) Stephen L. Rawlings, Ph.D. (3)_____.

(2) Kristina Bieker-Brady, Ph.D. (4)_____.

Date of Interview: 09 July 2002.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☐ No.
If Yes, brief description: _____.

Claim(s) discussed: _____.

Identification of prior art discussed: _____.

Agreement with respect to the claims f)☒ was reached. g)☐ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicant's Representative telephoned the Examiner to inquire about the restriction requirement that was mailed march 20, 2002 (Paper No. 8). It was determined that numerous inadvertent errors had been made in the restriction requirement. Therefore, the previous restriction requirement is withdrawn and will be replaced with another restriction requirment.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i)☐ It is not necessary for applicant to provide a separate record of the substance of the interview(if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case unless both applicant and examiner agree that the examiner will record same. Where the examiner agrees to record the substance of the interview, or when it is adequately recorded on the Form or in an attachment to the Form, the examiner should check the appropriate box at the bottom of the Form which informs the applicant that the submission of a separate record of the substance of the interview as a supplement to the Form is not required.

It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner's Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.



RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

FIRM:

PAGES, INCLUDING COVERSHEET:

PHONE NUMBER:

TO EXAMINER:

ART UNIT:

SERIAL NUMBER:

FAX/TELECOPIER NUMBER: (703) 308-4315

**PLEASE NOTE: THIS FACSIMILE NUMBER IS TO BE USED ONLY
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COMMENTS: _____

IF YOU HAVE NOT RECEIVED ALL THE PAGES OF THIS TRANSMISSION, PLEASE CONTACT THE ATTORNEY AT THE TELEPHONE NUMBER LISTED ABOVE.

IN COMPLIANCE WITH 1096 OG 30, THE FILING DATE ACCORDED EACH OFFICIAL FAX TRANSMISSION WILL BE DETERMINED BY THE FAX MACHINE DATE STAMP FOUND ON THE LAST PAGE OF THE TRANSMISSION, UNLESS THAT DATE IS A SATURDAY, SUNDAY, OR FEDERAL HOLIDAY WITHIN THE DISTRICT OF COLUMBIA, IN WHICH CASE THE OFFICIAL DATE OF RECEIPT WILL BE THE NEXT BUSINESS DAY.

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